PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 576.02-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/11693	International filing date *(day/month/year)* 26 MAY 1999	Priority date *(day/month/year)* 28 MAY 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant DUO MANAGEMENT INTERNATIONAL, LLC		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 DECEMBER 1999	20 SEPTEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MAUREEN WALLENHORST Telephone No. (703) 308-0661

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/11693

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-8 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 9-10 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages 1/4-4/4 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages none

[X] the claims, Nos. none

[X] the drawings, sheets/~~fig~~ none

5. [X] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/11693

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	3-11, 13-14	YES
	Claims	1-2, 12	NO
Inventive Step (IS)	Claims	none	YES
	Claims	1-14	NO
Industrial Applicability (IA)	Claims	1-14	YES
	Claims	none	NO

2. citations and explanations (Rule 70.7)

Claims 1-2 and 12 lack novelty under PCT Article 33(2) as being anticipated by Orell-Porrazzo et al. (WO 97/23798).

Orell-Porrazzo et al. teach of a method for determining a woman's fertility status which comprises the steps of providing an optical system having a sample receiving surface and an eyepiece, collecting a sample of bodily fluid from a woman, depositing the sample on the sample receiving surface, drying the sample, inspecting the sample using the optical system and correlating the appearance of the dried sample with a reference. The dried sample is inspected for a tell-tale, visual reference pattern of key, universal fertility carriers. A female secretion such as saliva is collected on a test area section 30 of the optical system. This test area section 30 serves as an integrated microscope stage. The saliva sample is allowed to dry completely. A viewing section 10 of the device is then rotated over the test area section 30 so that a user may visualize the pattern of fertility carriers in the sample of saliva. A central connecting joint 25 is located between the test area section 30 and the viewing section 10. This connecting joint 25 forms a rotating joint of determined fixed distance between the viewing section 10 and testing area section 30. This fixed distance 80 is selected to form an optimal viewing focal length between the microscope bead lens 15 and testing area section 30 of focal length 75. In the manufacturing process, the length of central connecting joint 25 and of its central connecting post 65 are made to the specification of distance 80 to accommodate focal length 75. In this way, the saliva sample is consistently viewed in focus through the optical system without having to alter the distance between the viewing section 10 and the test area section 30. The optical system may comprise a multi-lens system since multiple microscope bead lens 15 could be included consisting of different diameters creating different magnifying powers. In addition, an objective lens 23 and focusing lens 21 could be substituted for microscope bead lens 15 which are fashioned with a suitable focal length to provide a fixed focus to the test area section 30 and affording a magnifying power suitable to observe universal fertility carrier patterns.

(Continued on Supplemental Sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-14 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): On line 6 of claim 1, the phrase "the sample receiving portion" lacks antecedent basis since earlier in the claim, a sample receiving surface is positively recited.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:
The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): G01N 21/00, 21/03; 33/48 and US Cl.: 436/65, 164, 165, 906; 422/55, 58, 82.05; 600/551

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Claims 3-11 and 13-14 lack an inventive step under PCT Article 33(3) as being obvious over Orell-Porrazzo et al. in view of Cho. For a teaching of Orell-Porrazzo et al, see previous paragraphs.
Orell-Porrazzo et al. fail to teach a protective cover over the optical system, different geometrical arrangements for the optical system, and comparing the image of the dried saliva sample to a reference chart comprising a reference image from a fertile period, from a transition period and from an infertile period.

Cho teaches of a method and apparatus for determining a woman's fertile periods which comprises a hollow housing that sealably contains an optical system and a saliva specimen slide. The optical system is used to closely view patterns formed on the specimen slide by the saliva after it has dried and crystallized on the slide. The patterns are then compared with standard comparison patterns to determine the woman's present fertility status. The standard comparison patterns include patterns from an infertile period, a fertile period and a transition period. See lines 12-25 in column 5 of Cho. The device taught by Cho also has a cap member 60 that can be placed over the body portion 22a when the device is not in operation. The optical system has a lens assembly comprising a ring-shaped member 35 within which a pair of convex lens 36a and 36b are mounted. Cho teaches that various different known types of lenses in various configurations may be used in the device and method.

Based upon a combination of Orell-Porrazzo et al and Cho, it would have been obvious to one of ordinary skill in the art to compare the pattern from the dried saliva sample taught by Orell-Porrazzo et al. with standard patterns representing a fertile state, an infertile state and a transition state, as taught by Cho, so as to accurately assess the fertility status of the woman tested and determine what fertility state she is currently in. It also would have been obvious to one of ordinary skill in the art to provide the optical system taught by Orell-Porrazzo et al. with a protective cover such as the cap 60 disclosed in the device of Cho, so as to keep the optical system clean and protect the optical system from damage. It also would have been obvious to one of ordinary skill in the art to provide the optical system taught by Orell-Porrazzo et al. with different geometrical arrangements and with different known components such as a condenser or filter since Cho discloses that different known types of lenses in various configurations may be utilized in an optical system used to assess the fertility status of a woman.

Claims 1-14 meet the criteria set out in PCT Article 33(4), because the claims are directed to a method for determining a woman's fertility status.

---------- NEW CITATIONS ----------
NONE

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

Ir

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 576.02-PCT

Box No. I TITLE OF INVENTION

OPTICAL METHOD AND APPARATUS FOR DETERMINING FERTILITY STATUS

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DUO MANAGEMENT INTERNATIONAL, LLC
11811 W. Washington Place, Suite 312
Los Angeles, CA 90066
US

☐ This person is also inventor.

Telephone No.
310-397-5641

Facsimile No.
310-397-5101

Teleprinter No.

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

MOON, Margaret E.
11811 W. Washinton Place, Suite 312
Los Angeles, CA 90066
US

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

FISH, Robert D.
Crockett & Fish
1440 N. Harbor Blvd., Ste. 706
Fullerton, CA 92835
US

Telephone No.
714-449-2337

Facsimile No.
714-449-2339

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

VAUGHAN, Sheila C.
4161 Los Feliz Blvd., Ste. A1
Los Angeles, CA 90027
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

RAFFENSPERGER, M. Susan
215 7th St., Apt. B
Seal Beach, CA 90740
US

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- ☒ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SZ** Swaziland, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **CY** Cyprus, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **GW** Guinea-Bissau, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ **AL** Albania .....
- ☒ **AM** Armenia .....
- ☒ **AT** Austria . . and utility model .....
- ☒ **AU** Australia .....
- ☒ **AZ** Azerbaijan
- ☒ **BA** Bosnia and Herzegovina .....
- ☒ **BB** Barbados
- ☒ **BG** Bulgaria .....
- ☒ **BR** Brazil .....
- ☒ **BY** Belarus .....
- ☒ **CA** Canada
- ☒ **CH and LI** Switzerland and Liechtenstein
- ☒ **CN** China .....
- ☒ **CU** Cuba .....
- ☒ **CZ** Czech Republic . and utility model .....
- ☒ **DE** Germany . . and utility model .....
- ☒ **DK** Denmark . . and utility model .....
- ☒ **EE** Estonia . and utility model .....
- ☒ **ES** Spain .....
- ☒ **FI** Finland . and utility model .....
- ☒ **GB** United Kingdom
- ☒ **GD** Grenada
- ☒ **GE** Georgia .....
- ☒ **GH** Ghana .....
- ☒ **GM** Gambia
- ☒ **HR** Croatia .....
- ☒ **HU** Hungary .....
- ☒ **ID** Indonesia
- ☒ **IL** Israel .....
- ☒ **IN** India .....
- ☒ **IS** Iceland
- ☒ **JP** Japan .....
- ☒ **KE** Kenya .....
- ☒ **KG** Kyrgyzstan .....
- ☒ **KP** Democratic People's Republic of Korea .....
- ☒ **KR** Republic of Korea .....
- ☒ **KZ** Kazakhstan .....
- ☒ **LC** Saint Lucia
- ☒ **LK** Sri Lanka
- ☒ **LR** Liberia
- ☒ **LS** Lesotho .....
- ☒ **LT** Lithuania
- ☒ **LU** Luxembourg
- ☒ **LV** Latvia
- ☒ **MD** Republic of Moldova .....
- ☒ **MG** Madagascar .....
- ☒ **MK** The former Yugoslav Republic of Macedonia .....
- ☒ **MN** Mongolia
- ☒ **MW** Malawi .....
- ☒ **MX** Mexico .....
- ☒ **NO** Norway
- ☒ **NZ** New Zealand .....
- ☒ **PL** Poland .....
- ☒ **PT** Portugal .....
- ☒ **RO** Romania
- ☒ **RU** Russian Federation .....
- ☒ **SD** Sudan
- ☒ **SE** Sweden
- ☒ **SG** Singapore
- ☒ **SI** Slovenia .....
- ☒ **SK** Slovakia . . . and utility model .....
- ☒ **SL** Sierra Leone
- ☒ **TJ** Tajikistan .....
- ☒ **TM** Turkmenistan .....
- ☒ **TR** Turkey .....
- ☒ **TT** Trinidad and Tobago .....
- ☒ **UA** Ukraine .....
- ☒ **UG** Uganda .....
- ☒ **US** United States of America .....
- ☒ **UZ** Uzbekistan .....
- ☒ **VN** Viet Nam .....
- ☒ **YU** Yugoslavia .....
- ☒ **ZW** Zimbabwe .....

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☒ AE United Arab Emirates .....
- ☒ ZA South Africa .....
- ☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 28 May 1998 (28.05.98)	60/086,987	US		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): 1

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA / US

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*:

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	4 sheets
description (excluding sequence listing part)	:	8 sheets
claims	:	2 sheets
abstract	:	1 sheets
drawings	:	4 sheets
sequence listing part of description	:	0 sheets
Total number of sheets	:	18 sheets

This international application is **accompanied by** the item(s) marked below:

1. ☒ fee calculation sheet
2. ☒ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract:

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Robert D. Fish, Agent

For receiving Office use only

1. Date of actual receipt of the purported international application: 4 Rec'd PCT/PTO 28 NOV 2000
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET
Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's file reference: 576.02-PCT

Applicant: Duo Management International, LLC

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . . 240.00 [T]

2. SEARCH FEE . . . . . 700.00 [S]

International search to be carried out by US

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 19 sheets.

first 30 sheets . . . . . 455.00 [b1]

0 (remaining sheets) x 10.00 (additional amount) = 0.00 [b2]

Add amounts entered at b1 and b2 and enter total at B . . . . 455.00 [B]

Designation Fees

The international application contains 10 designations.

10 (number of designation fees payable *(maximum 10)*) x 105.00 (amount of designation fee) = 1,050.00 [D]

Add amounts entered at B and D and enter total at I . . . . . 1,505.00 [I]

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT *(if applicable)* . . . . . 15.00 [P]

5. TOTAL FEES PAYABLE . . . . . USD 2,460.00 TOTAL

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

☐ The designation fees are not paid at this time.

The PTO did not receive the following listed item(s)
~~No check for 2460.00~~
It is $50.00

MODE OF PAYMENT

- ☐ authorization to charge deposit account (see below)
- ☐ bank draft
- ☐ coupons
- ☒ cheque
- ☐ cash
- ☐ other *(specify)*:
- ☐ postal money order
- ☐ revenue stamps

DEPOSIT ACCOUNT AUTHORIZATION *(this mode of payment may not be available at all receiving Offices)*

The RO/ US

☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☒ *(this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

500341	25 May 1999	Robert D. Fish
Deposit Account No.	Date *(day/month/year)*	Signature

M·H

PCT/US99/11693

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 17 February 2000 (17.02.00)	
International application No. PCT/US99/11693	**Applicant's or agent's file reference** 576.02-PCT
International filing date (day/month/year) 26 May 1999 (26.05.99)	**Priority date** (day/month/year) 28 May 1998 (28.05.98)
Applicant MOON, Margaret, E. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

17 December 1999 (17.12.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

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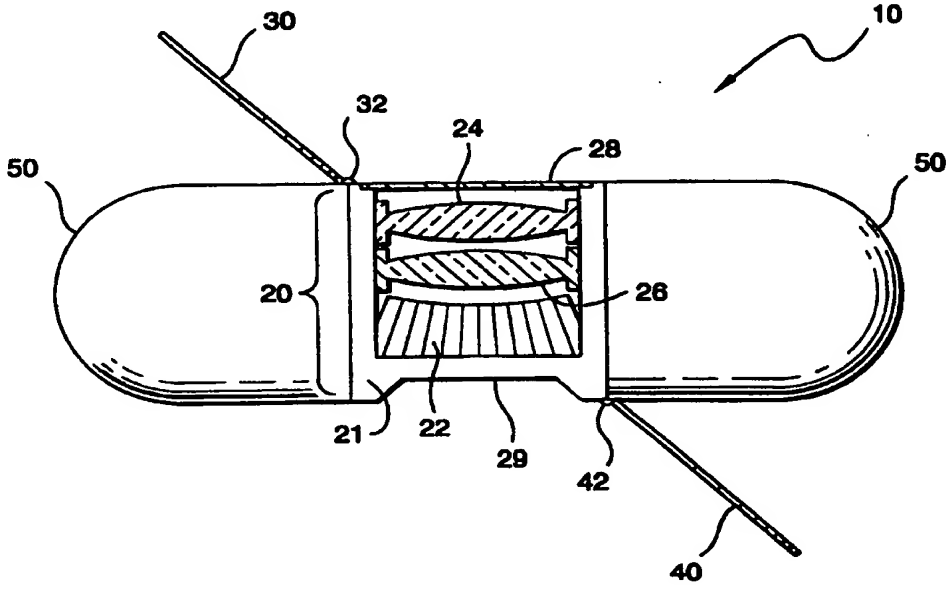

(57) Abstract

An optical method of determining a woman's fertility status is provided, wherein an optical system (20) has a sample receiving surface (29) and an eyepiece (28), such that the sample can be viewed in focus through the optical system (20) without altering the distance between the eyepiece (28) and the sample receiving surface (29) using ambient–light illumination. A sample of a bodily fluid from a female is deposited at the sample receiving surface (29) of the optical system (20) and dried. The dried sample is then inspected using the optical system (20) and the appearance of the dried sample is correlated with a reference.

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OPTICAL METHOD AND APPARATUS FOR DETERMINING FERTILITY STATUS

This application claims the benefit of U.S. provisional application number 60/086,987 incorporated herein by reference in its entirety.

Field of The Invention

The field of the invention is biomedical diagnostics.

Background of The Invention

Conception typically occurs during the period of the menstrual cycle called "ovulation" in humans, which is expected to last about six days. Monitoring ovulation is of great significance, because knowing the time of ovulation enables women to manage their reproductive period. When pregnancy is desired, monitoring of ovulation can be used to find the relatively narrow window of fertility within a menstrual cycle. When pregnancy is not desired, monitoring ovulation can be used as an alternative to classical methods of contraception by determining times of sexual abstinence or use of contraceptives.

Many ways of monitoring ovulation are known in the art, and may be broadly characterized as falling within one of two categories. The first category of monitoring ovulation comprises clinical diagnostic methods that are typically available only in hospitals or in a physicians office. Clinical diagnostic methods include sonography, and ELISA based methods to quantify various reproductive hormones. Such methods are relatively accurate, however, clinical diagnostic methods typically involve a significant cost and inconvenience to the patient.

The second category of monitoring ovulation comprises "home" diagnostic methods. Home diagnostic methods can typically be performed with a minimal amount of equipment, and generally rely on simple physical or biochemical observations. Physical observations include, for example, the monitoring of the woman's body temperature. Body temperature testing is based upon the fact that a woman's normal body temperature rises slightly during ovulation. However, improper technique of determining the body temperature may lead to significant inaccuracy. Furthermore, minor infections, stress, and dietary influences may cause fluctuations in the body temperature and make this method relatively inaccurate. Biochemical observations include quantitative tests of reproductive hormones in urine. For example, home tests to determine the

level of luteinizing hormone or progesterone in urine are commercially available over the counter. Home based urine tests are typically easy to perform, and require little time. However, home based urine tests tend to be expensive, especially when repeated over a longer period of time.

The time of ovulation can also be determined by observing the appearance of crystallized saliva (i.e. saliva that has been allowed to dry at room temperature). It is known in the art that hormonal changes during a woman's menstrual cycle affect the appearance of crystallized saliva, manifested as formation of characteristic crystals that can be observed using a magnification device (see Figure 1).

Determination of ovulation by microscopic observation of crystallized saliva is advantageous because it is inexpensive, relatively accurate and follows a simple protocol that allows even the inexperienced user to obtain reliable test results. Moreover, microscopic observation of crystallized saliva is accurate even when menstrual cycles are erratic, ovulation is irregular, or menstrual disturbances are experienced. Furthermore, microscopic observation of crystallized saliva is a non-invasive and painless method that can be performed discretely and relatively quickly.

Various optical systems are known in the art to help determine ovulation by microscopic observation of crystallized saliva. U.S. Pat. No. 4,737,016 to Russell et al., for example, describes a portable handheld microscope with a single lens. Although the portable handheld microscope can be used to observe a crystallized saliva sample, it is originally designed to view small insects or other small objects, and sample handling is therefore rather cumbersome.

In another example, U.S. Pat. No. 5,062,697 to Mitchell, a handheld microscope is presented wherein a test sample can be compared with a reference sample in a single step. However, manual focussing is required, complicating the use of the device. Furthermore, batteries and an intact light bulb are needed to provide transillumination of the sample.

In a further example, U.S. Pat. No. 5,639,424 to Rausnitz, up to 30 samples can be viewed on a sample disc in a portable fertility tester. The sample disc, however, introduces an additional part that is essential to the function of the tester. If the disc is broken or lost, no more

tests can be performed. Moreover, the advantage of accommodating up to 30 samples disadvantageously leads to a larger test device.

In still further examples, U.S. Pat. No. 5,572,370 to Cho, and U.S. Pat. No. 4,815,835 to Ortueta Corona, fertility testers are described, in which the optical device has to be disassembled in order to apply a sample of saliva. Disassembling, applying the sample, reassembling and adjusting the focus of the fertility tester, and holding down the light switch, however, requires at least some degree of dexterity, which might be problematic for some users.

Viewing a magnified crystallized saliva sample using lenses typically requires a relatively strong light source. Most known fertility testers use batteries and a light bulb or an LED as a light source, which tends to be problematic in some countries, especially in third world countries. Moreover, the use of batteries demands appropriate battery recycling when a negative impact to the environment is to be avoided.

The fertility tester "PFT 1-2-3" avoids problems with built-in backlighting devices by using ambient light. In the "PFT 1-2-3", various color filters are mounted on one disc and a miniature lens is mounted on a second disc. Both discs are rotatably connected at their center, and lens and color filter have to be aligned by turning the miniature lens-containing disc relative to the filter-containing disc to examine a crystallized saliva sample. Although the two discs are spaced in such a way that the crystallized saliva sample is in focus, the miniature lens does not allow substantial tolerance in the distance between the two discs. Therefore, manual pressure has often to be applied to both discs in order to refocus. Moreover, due to the small size of the magnifying lens, the observation area is relatively small.

In most or all devices known in the art to visually inspect a crystallized saliva sample, an optical system must be focused. To obtain a sharp image of the crystallized saliva, the distance between the crystallized saliva and an eyepiece is usually altered. However, focussing an optical system usually requires some practice and may be cumbersome, especially for the inexperienced user. Moreover, focusing optical systems typically requires moving parts that may be subject to malfunction, possibly leading to false-positive or false-negative test results.

In general, many devices to determine ovulation by observing crystallized saliva are known. However, such devices typically suffer from one or more difficulties including problematic sample application, need of an internal light source, or problematic focussing of the eyepiece on the sample. Therefore, there is a need to provide apparatus and methods to solve these problems.

Summary of the Invention

Methods and apparatus for determining a woman's fertility status are provided in which a sample is consistently viewed in focus through an optical system, without altering the distance between the eyepiece and the sample receiving surface.

In preferred embodiments the optical system includes at least two lenses, and optionally includes a filter. It is also preferred that the bodily fluid is saliva or vaginal fluid.

Various objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description of preferred embodiments of the invention, along with the accompanying drawings in which like numerals represent like components.

Brief Description of The Drawings

Figure 1 is a collection of prior art photomicrographs of samples of crystallized saliva.

Figure 2 shows a schematic of a fertility tester embodying the inventive subject matter.

Figure 3 shows a top view of the fertility tester of Figure 2.

Figure 4 shows general outlines of alternative shapes of the fertility tester of Figure 2.

Detailed Description

In Figure 2, a fertility tester 10 has generally an optical system 20, a top cover 30, a bottom cover 40, and a case 50. The optical system 20 has an optical chamber 21, a condenser 22, a first lens 24, a second lens 26, a protective window 28, and a sample receiving surface 29.

With respect to the material of preferred fertility tester 10, all parts can be fabricated from injection-molded acrylic. However, many other materials may also be used, including natural and synthetic polymers, metals and glass and any reasonable combination thereof. For example, appropriate alternative materials are polycarbonate, polyethylene, wood, aluminum, and optical glass.

Fertility tester 10 is shown in Figures 2 and 3 as a round disk. Various other shapes, however, are also contemplated, including rectangular and polygonal shapes. Some examples of alternative shapes are shown in Figure 4 and many more alternative shapes can be made without departing from the inventive concepts presented herein.

Fertility tester is preferably approximately 5" in diameter and about 1.5" thick. However, many other dimensions are also contemplated as long as they accommodate optical system 20.

Cover 30 and cover 40 are preferably coupled to case 50 using acrylic hinges 32 and 42. However, many other covers and methods of affixing covers to case 50 are contemplated, that cover the protective window and the sample receiving surface. For example, alternative covers could be pivotably, slidably or rotatably coupled to case 50, and may or may not be permanently attached to case 50.

It is contemplated that case 50 may comprise additional elements, including a pocket, a mirror, a chart to enter fertility status, reference pictures of crystallized saliva, instructions for use, etc. It is further contemplated that case 50 need not necessarily have a top cover or a bottom cover. Alternative fertility testers may therefore have only optical system 20, case 50 and bottom cover 40.

Optical system 20 further comprises optical chamber 21, protective window 28, first lens 24, second lens 26, condenser 22, and sample receiving surface 29.

Optical chamber 21 is preferably statically mounted in case 50. In alternative embodiments, however, many other ways of mounting the optical chamber to a case are contemplated, including mountings wherein the optical chamber is slideably, pivotably or rotatably coupled to a casing.

Optical chamber 21 is preferably made from non-transparent, tinted, injection-molded acrylic. Optical chamber 21 contains a multi-lens system of two bi-convex acrylic lenses 24, 26, each of which are molded to two annular acrylic spacer elements. Optical chamber 21 further comprises an acrylic protective window 28 opposite to the sample receiving surface 29. In alternative embodiments, various other materials may be used for optical chamber, lenses, annular spacers, and protective window, including transparent synthetic polymers, glass, and metals. For example, alternative lenses may be made from optical glass or polystyrene, annular spacers may be made from polypropylene, optical chambers may be made from steel or brass, and an alternative protective window may be made from transparent polyvinyl chloride.

In Figure 2, the bi-convex lenses 24, 26 are prefocused to the sample receiving surface 29, and have a combined magnification of preferably 40x-100x, and more preferably 50x-60x. However, many other arrangements of optical elements are also contemplated, including single lenses, multiple lenses of various characters (e.g. bi-convex, bi-concave, convex-concave, etc.), condenser elements, and filters. For example, contemplated lens systems include systems having two bi-convex and one plano-concave lens. A single lens with an 85x magnification is also contemplated. Contemplated condenser elements may be reflective, refractive, or diffractive. The condenser element may be used to enhance illumination of the sample, for example, using dark-field illumination to increase the contrast of the sample. Appropriate filters include polarizing filters, spectral cut-off filters, or filter groups.

In a preferred embodiment, sample receiving surface 29 is a transparent, approximately 1mm thin, rounded off square surface, which is an integral part of optical chamber 21. In alternative embodiments, sample receiving surface 29 may be separable from optical chamber 21. For example, an alternative sample receiving surface includes a glass or transparent polymer surface that may or may not be tinted.

Regardless of the arrangement and number of optical elements in optical system 20, the optical elements are situated such that the optical system is prefocused with regard to sample receiving surface 29.

The term "depositing the sample" as used herein means that the sample is transferred directly or indirectly from the source to the sample receiving surface. A direct transfer, for

example, is licking the surface of the sample receiving surface. An indirect transfer, for example, is applying vaginal fluid from a vaginal swab to the sample receiving surface.

As used herein, the term "bodily fluid" refers to saliva and vaginal fluid and the bodily fluid may be manually collected or with the help of a sampler. Typically, a few microliters of bodily fluid are sufficient for determining the fertility status.

As used herein, the term "ovulation" and "fertile period" are used interchangeably, and both reflect the time during a menstrual cycle during which conception is possible.

As used herein, the term "eyepiece" refers to the lens closest to the eye.

In a preferred method of determining a woman's fertility status, a woman transfers a drop of saliva from her mouth onto a fingertip. The saliva on the fingertip is then wiped over the sample receiving surface. In alternative embodiments, the bodily fluid need not be saliva, but may be various other bodily fluids, including vaginal fluid. Moreover, the bodily fluid need not be transferred onto a fingertip, but may also be transferred in other ways, including direct and indirect application. For example, direct application includes dripping of saliva from the mouth onto the sample receiving surface. An example of indirect application is swabbing the surface of a woman's inner cheek with an applicator, and then wiping the applicator over the sample receiving surface.

The saliva on the sample receiving surface is then dried, preferably at room temperature for about 10min. However, many other ways of drying are also contemplated, including drying at temperatures above or below room temperature. For example, drying may be performed at temperatures of about 30°C to 60°C, or even higher. In another example, drying may be done at temperatures between about 4°C-20°C. Furthermore, the time of drying need not be restricted to 10min, but may vary considerably between a few seconds and several hours, depending on the temperature and amount of bodily fluid. Appropriate drying times are, for example, 10 to 30 seconds, but also 30 minutes, and longer.

After drying the bodily fluid on the sample receiving surface, the bodily fluid is inspected using the optical system, and the appearance of the bodily fluid is correlated with a reference. During inspection, the fertility tester is preferably held such that ambient light passes through the

bodily fluid and eyepiece into the eye of the observer. The protective window is preferably at a distance of about ½" to 1" from the eye of the observer, and the sample receiving surface points toward an ambient light source.

In a preferred embodiment, the ambient light source is preferably an incandescent light bulb. However, in alternative embodiments the ambient light source may be various other light sources including sunlight, fluorescent light bulbs, etc. Furthermore, it is not essential that the protective window is at a distance of ½" to 1" from the eye of the observer, but many other distances are also contemplated.

The reference is preferably a reference chart as depicted in Figure 1 that shows three magnified images of dried saliva, corresponding to a period that is regarded as fertile, possibly fertile, and infertile. In alternative embodiments, however, many other references may be used, including memorized images of dried bodily fluids, and sample images that can be viewed together with dried bodily fluid. In further alternative embodiments, the number of reference images need not be limited to three, but may vary between one and 28, or even more. In still further alternative embodiments, the reference may include additional elements, including a report chart in which test results can be noted.

Thus, specific embodiments and applications of determining a woman's fertility status have been disclosed. It should be apparent, however, to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the appended claims.

CLAIMS

What is claimed is:

1. A method of determining a woman's fertility status comprising:

providing an optical system having a sample receiving surface and an eyepiece, such that a sample is consistently viewed in focus through the optical system without altering a distance measured between the eyepiece and the sample receiving surface;

providing a sample of a bodily fluid from a female;

depositing the sample at the sample receiving portion;

drying the deposited sample and inspecting the dried sample using the optical system; and

correlating the appearance of the dried sample with a reference.

2. The method of claim 1, wherein the optical system comprises a multi-lens system.

3. The method of claim 2, wherein the geometry of at least one lens is a mirror image of another lens.

4. The method of claim 1, wherein the optical system further comprises a condenser.

5. The method of claim 4, wherein the condenser reflects light through the dried sample.

6. The method of claim 4, wherein the condenser is a refractive condenser.

7. The method of claim 1, wherein the optical system further comprises a filter.

8. The method of claim 1, further comprising providing a protective cover over the optical system.

9. The method of claim 8, wherein the protective cover comprises at least one of a top cover and a bottom cover.

10. The method of claim 9, wherein the at least one of a top cover and a bottom cover is slideably coupled to the optical system.

11. The method of claim 9, wherein the at least one of a top cover and a bottom cover are pivotably coupled to the optical system.

12. The method of claim 1, wherein the bodily fluid of a female is selected from the group consisting of saliva and vaginal fluid.

13. The method of claim 1, wherein the step of drying the sample comprises air drying at room temperature for 10min.

14. The method of claim 1, wherein the reference is a reference chart comprising at least one reference image from a fertile period, one reference image from a transition period, and one reference image from a infertile period.

AMENDED CLAIMS

[received by the International Bureau on 2 November 1999 (02.11.99); original claim 1 amended; remaining claims unchanged (1 page)]

1. A method of determining a woman's fertility status comprising:

providing an optical system having a non-removable sample receiving surface and an eyepiece, such that a sample is applied to the sample receiving surface and consistently viewed in focus through the optical system without altering a distance measured between the eyepiece and the sample receiving surface;

providing a sample of a bodily fluid from a female;

depositing the sample at the sample receiving portion;

drying the deposited sample and inspecting the dried sample using the optical system; and

correlating the appearance of the dried sample with a reference.

2. The method of claim 1, wherein the optical system comprises a multi-lens system.

3. The method of claim 2, wherein the geometry of at least one lens is a mirror image of another lens.

4. The method of claim 1, wherein the optical system further comprises a condenser.

5. The method of claim 4, wherein the condenser reflects light through the dried sample.

6. The method of claim 4, wherein the condenser is a refractive condenser.

7. The method of claim 1, wherein the optical system further comprises a filter.

8. The method of claim 1, further comprising providing a protective cover over the optical system.

9. The method of claim 8, wherein the protective cover comprises at least one of a top cover and a bottom cover.

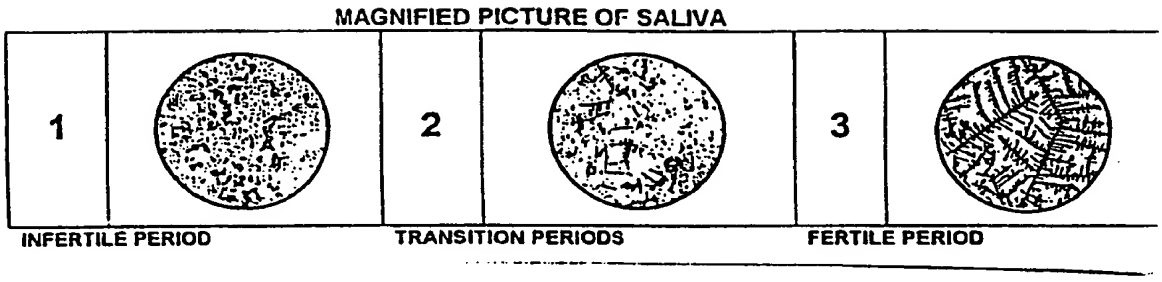
MAGNIFIED PICTURE OF SALIVA
1
2
3
INFERTILE PERIOD
TRANSITION PERIODS
FERTILE PERIOD

Figure 1

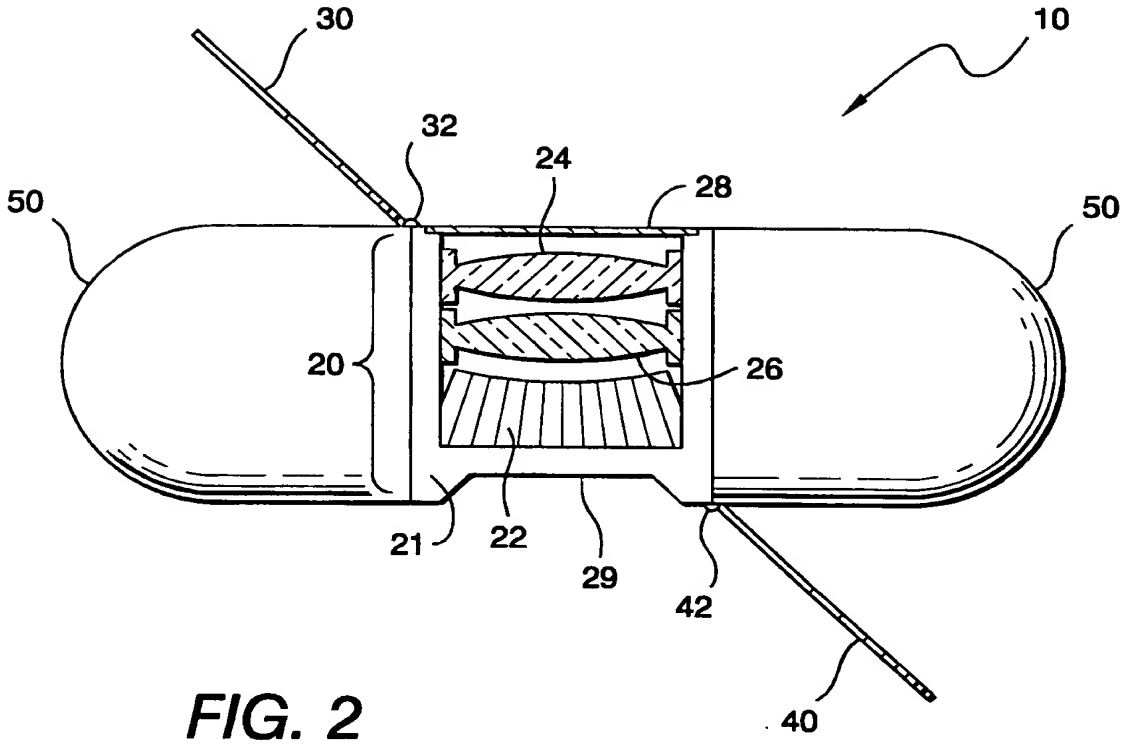

FIG. 2

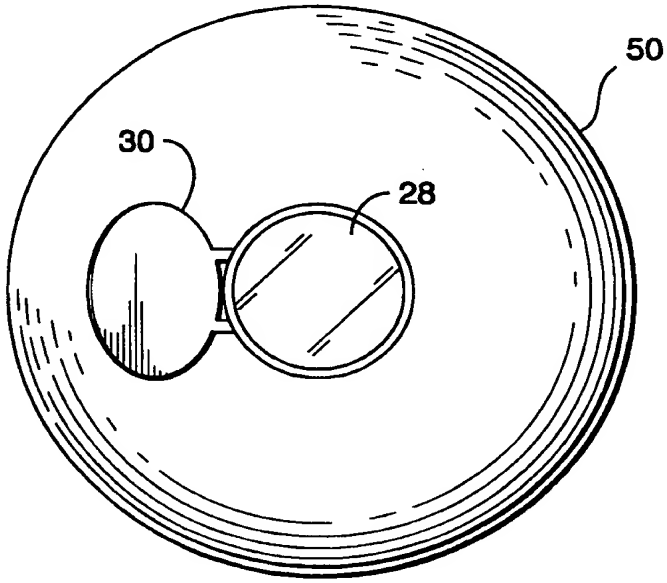

FIG. 3

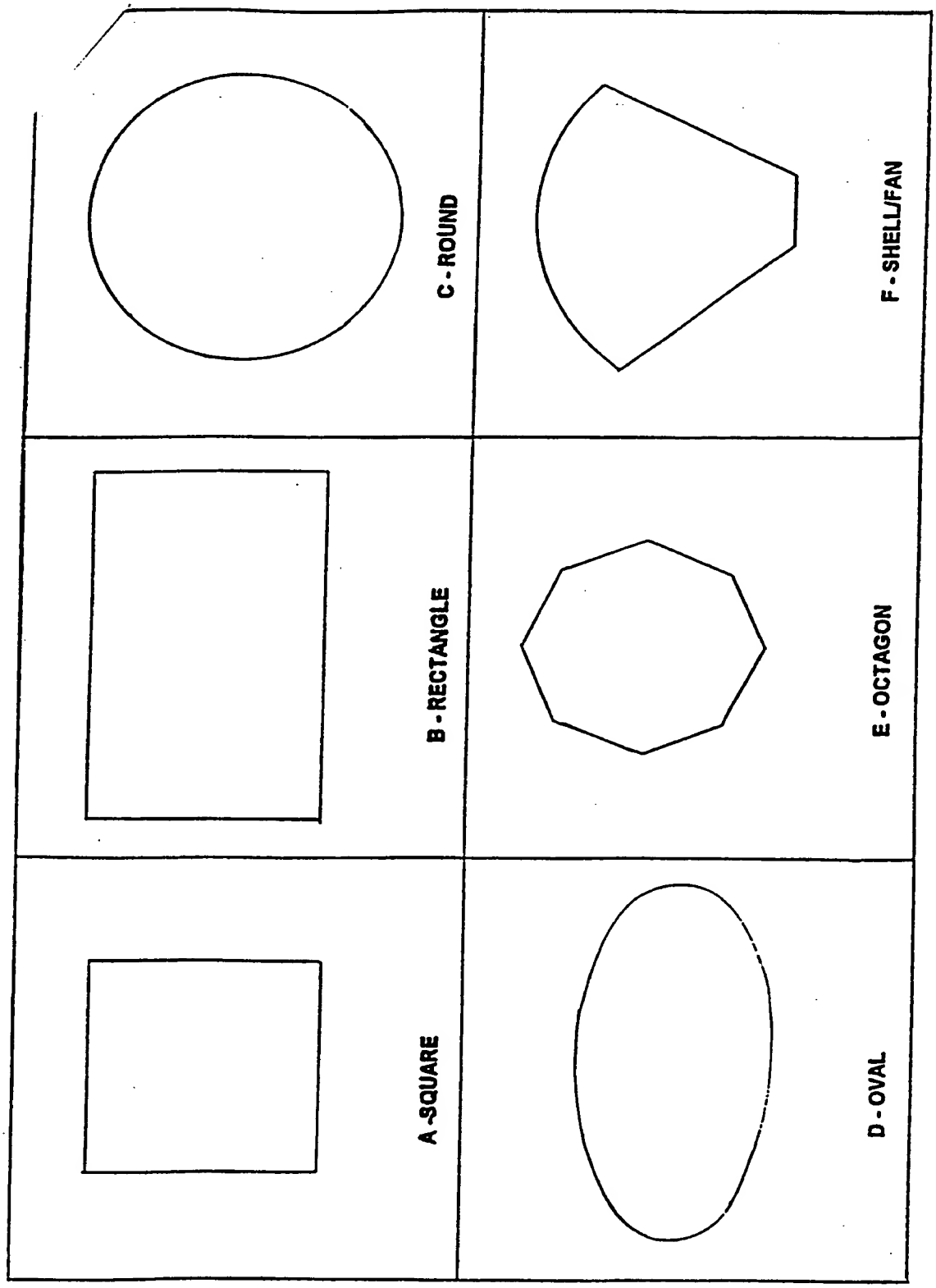

Figure 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/11693

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G01N 21/00, 21/03; 33/48

US CL :436/65, 164, 165, 906; 422/55, 58, 82.05; 600/551

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 436/63, 65, 164, 165, 174, 814, 906; 422/55, 58, 82.05; 600/310, 551; 359/396, 398, 801, 803, 804

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STN/CA, BIOSIS, MEDLINE, DERWENT
search terms: fertility, saliva, optical, prefocused, fixed distance

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 97/23798 A1 (ORELL-PORRAZZO et al.) 03 July 1997, pages 24, 36-38 and 48.	1-2, 12, 14 --- 3-7, 8-11, 13
Y	US 5,572,370 A (CHO) 05 November 1996, column 3, lines 1-26, column 4, lines 48-68 and column 5, lines 1-28.	3-7, 8-11, 13
A	US 4,815,835 A (ORTUETA-CORONA) 28 March 1989, column 3, lines 51-68 and column 4, lines 1-61.	1-14
A	US 5,267,087 A (WEIDEMANN) 30 November 1993, column 4, lines 14-68 and column 5, lines 1-9.	1-14

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of the actual completion of the international search 05 AUGUST 1999	Date of mailing of the international search report 02 SEP 1999
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/11693

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,639,424 A (RAUSNITZ) 17 June 1997, column 3, lines 9-68 and column 4, lines 1-14.	1-14